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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/677,982	10/01/2003	Philip A. Beachy	JHU1510-2	9078

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EXAMINER

MCKELVEY, TERRY ALAN

ART UNIT PAPER NUMBER

1636

DATE MAILED: 03/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/677,982

Applicant(s)

BEACHY ET AL.

Examiner

Terry A. McKelvey

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 52-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 52-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/1/03</u> | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1636

DETAILED ACTION

Election/Restrictions

In applicant's response filed 1/10/05, it is noted that the claims had been previously amended and that there is no restriction requirement for the pending claims. This is correct, the previous restriction requirement is hereby withdrawn, and pending claims 52-57 have been examined as follows.

Information Disclosure Statement

It is noted that the IDS filed 10/1/03 comprised copies of IDS's and 892 forms from parent applications that were previously initialed and signed. Although there is no current rule against this, it is confusing because the date of review would be unclear without further action being taken. Therefore, the examiner crossed-out the previous initials, dates, signatures, and parent case information, before initialing, signing and dating for the instant application. It is suggested that applicant avoid this type of IDS submission in future IDS's and applications.

Art Unit: 1636

Priority

The claim of priority to 09/934,035 is noted in the first sentence of the specification. The claim of priority should be amended to reflect the new status of this application as U.S. Patent No. 6,733,971.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 52-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The preamble of claim 52 recites: "A method of identifying a compound that inhibits a phosphatase involved in a hedgehog signaling pathway comprising:" and the last step recites: "measuring the ability of the compound to affect the hedgehog signaling pathway by detecting an increase or decrease in the expression of the target gene". The claims are vague and indefinite because the method steps do not result in what the preamble indicates and thus it is unclear whether the claimed

Art Unit: 1636

method is a method as recited in the preamble or a method as defined by the method steps. First, there is no correspondence between affecting expression of the target gene and incubation of the components because only the compound, the transcription factor, and the phosphatase are indicated as being incubated. There is no indication of the incubation of the hedgehog response element operatively associated with a target gene. Assuming that the element associated with the target gene is present (i.e., if this was added by amendment), the result of the method steps is identification of a compound that affects the hedgehog signaling pathway, which is different from identification of a compound that inhibit a phosphatase involved in a hedgehog signaling pathway. The method steps do not distinguish the effect of the compound on other parts of the hedgehog signaling pathway, such as affecting the binding of the transcription factor to the HRE (see page 33, lines 19-22 of the instant specification), or other specific or non-specific effects. Also, since either an increase or decrease of expression is assayed, this is different from only assaying the inhibition of a phosphatase. Amending the preamble and/or method steps to result in a correspondence between the preamble and what the method steps accomplish would be remedial.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 52 and 55-57 are rejected under 35 U.S.C. 102(a) as being anticipated by Krishnan et al (Applicant IDS reference AE).

Krishnan et al teach an assay for the role of protein phosphatases by transfecting P19 cells with sonic hedgehog response element-luciferase reporter plasmid along with OA (a phosphatase inhibitor (Figures 3 and 4)). This reads on incubating the compound (the inhibitor), a transcription factor (naturally present in the cell), and a phosphatase (also naturally present in the cell), under conditions sufficient to allow the components to interact, and the increase or decrease of expression from the luciferase reporter is measured (Figures 3 and 4). Although the reference does not teach that transcription factor was specifically identified using the method described in claim 57, the transcription factor in the P19 cells could be identified by such a method and thus is the

Art Unit: 1636

same as a transcription factor that was identified in such a fashion, and thus the teachings of Krishnan et al also apply to claim 57.

Conclusion

No claims are allowed.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is 571-273-8300. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance.

Art Unit: 1636

Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Terry A. McKelvey whose telephone number is (571) 272-0775. The examiner can normally be reached on Monday through Friday, except for Wednesdays, from about 7:30 AM to about 6:00 PM. A phone message left at this number will be

Art Unit: 1636

responded to as soon as possible (i.e., shortly after the examiner returns to his office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached at (571) 272-0781.



Terry A. McKelvey, Ph.D.
Primary Examiner
Art Unit 1636

March 21, 2005